



By Electronic Mail

June 29, 2020

Patricia Biggio, Chemical Review Manager
Pesticide Reevaluation Division (7508P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Tetrachlovinphos (TCVP): Response to EPA email June 26, 2020

Dear Ms Biggio:

1. Cat collar label change 2596-49:

- a. Based on previous production trends (2017 – 2020, 0 units produced), please confirm that Hartz is not planning to produce more product. Hartz confirms, it is not planning to produce additional collars using the existing registered label; however, Hartz upon approval of the amended registration and label (Appendix 1) reserves the right to manufacture and market the product under the new amended label. The amended label, as discussed and agreed, contains the addition of a greater than five (5) pound weight restriction.
- b. Based on the production information provided to us by Hartz, we do not see the need for such a long sell-off period. Please provide us more information. The product does not require a sell off, since no inventory exists and none is planned. The sell off was a part of the entire package of registered collars including Registrations 2596-83;-84 and -139 which do require a sell off (see below). Label amendment is submitted with this email and will be filed via EPA portal.
- c. If there is currently no inventory for this product, the EPA suggests that Hartz state any production would start after the new label is approved. Hartz has agreed to provide a label amendment by June 30, 2020 and it is expected that the agency could review this amendment quickly. Hartz as stated above agrees that all new production will start upon the receipt of the approved amended label, which EPA agrees will receive an expedited review.

2. Collars 2596-50 and 2596-62:

- a. Based on previous production trends (2017 – 2020, 0 units produced), please confirm that Hartz is not planning to produce more product. Hartz confirms, it is not planning to produce additional collars using the existing registered label; however, Hartz upon approval of the amended registration and label (Appendix 2 and 3) reserves the right to manufacture and market the product under the new amended label.
- b. Please confirm if there is existing inventory or already-manufactured product awaiting sale or distribution. If not, a sell-down period until December 31, 2021 is not necessary for these products. Please provide inventory information to support this date. The

product does not require a sell off since no inventory exists and none is planned. The selloff was a part of the entire package of registered collars including Registrations 2596-83;-84 and -139 which do require a sell off (See below). Label amendment is submitted with this email and will be filed via EPA portal

- c. If there is no existing inventory for distribution, please confirm if Hartz agrees that no production, sale and distribution is allowed until a design change is approved. Hartz, as stated above, agrees that all new production will start upon the receipt of the approved amended label, which EPA agree will receive an expedited review.
3. Collars 2596-83, 2596-84, and 2596-139: While both Hartz and EPA are hopeful that the replacement designs can be approved expeditiously, unforeseen circumstance may unexpectedly extend the time to review the amendments for these products. Would Hartz agree to a contingency plan to request voluntarily cancellation effective on the date that production would cease (December 31, 2021) for the old version of the collars, with existing stocks to be sold through the date of the sell-down period, if the registrations have not been amended to approve a new design by June 30, 2021? Hartz has prepared amended labels (Appendix 4 and 5) with this email. Hartz's amendment has been discussed and fully explained to the Agency. Hartz has filed and discussed with EPA the necessary refinement to increase the Margin of Exposure. More importantly, the MOE as calculated by the Agency are acceptable for medium and large dogs; therefore, current data supports the use on these dog sizes. The collar is extruded, and the basic formulation remains the same: therefore, product chemistry remains unchanged. The weight of the collar per square inch has changed, but the chemistry of the formulation used to make the collar remains constant. A review of the product chemistry shows that all of the chemical measurements remain the same. The dimensions of the collar are not currently a part of the registration data. Hartz is supplying below in Table 1 and 2 the revised dimensions, and has supplied the efficacy bridging data in a separate submission. Given the minimal data for review and the cooperation of the registrant after discussions with the Agency, Hartz believes there is ample time for the Agency to review and approve the revised registration prior to July 20, 2020, and will not include a contingency for voluntary cancelation.

Table 1

Current Collar Specifications

	Total Length	Effective Length	Width	Thickness	Total Weight (g) (g/inch)
Cat	13"	12"	(0.43-0.445)	(0.153-0.161)	16.12-17.18
Sm. Dog	16"	15"	(0.43-0.445)	(0.153-0.161)	19.84-21.92
Reg. Dog	21"	20"	(0.43-0.455)	(0.153-0.161)	26.04-28.77
Lg. Dog	27"	26"	(0.43-0.455)	(0.153-0.161)	33.48-36.99

Table 2

Revised Collar Specifications

	Total Length	Effective Length	Width	Thickness	Total Weight (g/inch)
Cat	13"	12"	(0.35-0.370)	(0.126-0.132)	10.14-11.44
Sm. Dog	16"	15"	(0.35-0.370)	(0.126-0.132)	12.48-14.08
Reg. Dog	21"	20"	(0.35- 0.370)	(0.126-0.132)	16.38-18.48
Lg. Dog	27"	26"	(0.35-0.370)	(0.126-0.132)	21.06-23.76

4. Please provide production reports for the dust powder products, 2596-78 and 2596-79, for 2017, 2018, 2019, and 2020.

Table 3

Production Units

	2017	2018	2019	2020
Registration No. 2596-83(cat)	278,328	170,400	231,432	152,440
Registration No. 2596-84(dog)	152,376	96,984	51,768	50,000

Hartz will continue to work with EPA and requests that any questions be referred to JoeConti at hartz.com or via my cell phone since our office remains closed during the pandemic at 551.697.0608.

Sincerely,

Joe Conti

JoeConti
Sr. Director Regulatory, Research & Development

Cc: Dana Friedman (EPA)

NOTICE: This communication may contain privileged or other confidential information. If you are not the intended recipient, or believe you have received this communication in error, please delete the copy you received, and do not print, copy, retransmit, disseminate, or otherwise use the information. Thank you.